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Congress of the United States
House of Representatives
Washington, DC 20515-2107

March 16, 2010

The Honorable Kathleen Sebelius
Secretary
Department of Health and Human Services
Washington, D.C. 20201

Dear Madame Secretary:

I am writing to urge you to request that the President's Science Advisor, Dr. John Holdren, reverse the actions of his predecessor which effectively block your agency from moving forward to distribute potassium iodide (KI) to Americans living within a 20 mile radius of a nuclear power plant, thereby protecting them from the cancer-causing releases of radioactive iodine that would occur if a nuclear disaster occurred in the United States.

I have read in media reports that a spokesperson from the Department of Health and Human Services (HHS) that "Policy options relating to KI distribution will be among the issues studied."[1] In fact, this issue has already been very been thoroughly studied. We need to get your agency back in a position to make KI available to the public, and to do that, Dr. Holdren needs first to take action.

In 2002, I authored Section 127 of the Bioterrorism Preparedness and Response Act, which directed the President to establish a program to make KI available to State and local governments for distribution to residents living within 20 miles of a nuclear power plant. Previously, distribution was limited to just those within 10 miles, and only at the States' initiatives. In a subversion of the intent of the Congress, the Bush White House chose to deny communities free access to this potentially life-saving drug. The Obama Administration has continued to ignore the law, despite my urging the Administration to implement the law in 2009.[2] [3]

KI is a safe, stable, and inexpensive compound that has been approved by the Food and Drug Administration (FDA) for the protection of the public, particularly children and pregnant women, against radiation-induced cancers in the event of a nuclear emergency. Potassium iodide prevents uptake by the body of radioactive iodine, which causes thyroid cancer. One need only look at cancer rates after the Chernobyl disaster: those who had

[1] http://www.reuters.com/article/2011/03/16/us-japan-quake-iodide-distribution-idUSTRE72F09G20110316?feedType=RSS&feedName=topNews
[2] http://markey.house.gov/index.php?option=com_content&task=view&id=3816&Itemid=141
[3] http://markey.house.gov/index.php?option=com_content&task=view&id=4257&Itemid=141

taken KI were far less likely to develop radiation-induced cancers.[4] As the nuclear catastrophe unfolds in Japan, one hopeful piece of information is that the Japanese government has distributed potassium iodide pills to the evacuation centers taking in the hundreds of thousands of residents who lived near the reactors that are spewing radiation.

The essential value of distributing potassium iodide in preparation for a potential nuclear disaster has been abundantly clear for more than 30 years.

The 1979 Kemeny Commission on the Three Mile Island accident called for "An adequate supply of the radiation protective (thyroid blocking) agent, potassium iodide for human use, should be available regionally for distribution to the general population and workers affected by a radiological emergency."[5] The Commission noted that when the accident occurred, there were not "quantities sufficient for the population within a 20-mile radius of TMI," leading officials to scramble to try to procure potassium iodide for these residents. The FDA had approved potassium iodide in 1978.

I held a hearing on KI in March 1982 that also established the strong evidence for a federal policy providing for pre-distribution of potassium iodide.

In the *Federal Register* of June 29, 1982, the FDA announced final recommendations on the administration of KI to the general public in a radiation emergency.

In January 2001, the NRC issued a rule providing funding for a supply of potassium iodide for those states that requested it.[6] Thirty-four states have eligible residents within 10 miles in the Emergency Planning Zone around nuclear power plants.

In December 2001, the FDA issued updated guidance on dosages of KI, concluding that ***"across populations at risk for radioiodine exposure, the overall benefits of KI far exceed the risks of overdosing, especially in children, though we continue to emphasize particular attention to dose in infants."***[7]

The FDA also stated that, "As in our 1982 notice in the *Federal Register*, FDA continues to recommend that radiation emergency response plans include provisions, in the event of a radiation emergency, for informing the public about the magnitude of the radiation hazard, about the manner of use of KI and its potential benefits and risks, and for medical contact, reporting, and assistance systems. FDA also emphasizes that emergency response plans and any systems for ensuring availability of KI to the public should recognize the critical importance of KI administration in advance of exposure to radioiodine."

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[4] Nauman J, Wolff J. (1993) Iodide prophylaxis in Poland after the Chernobyl reactor accident: Benefits and risks. *The American Journal of Medicine*, Volume 94, Issue 5, Pages 524-532.

[5] http://www.threemileisland.org/downloads/188.pdf.

[6] http://www.nrc.gov/about-nrc/emerg-preparedness/protect-public/ki-files/ml020150357.pdf

[7] http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm080542.pdf

My 2002 amendment to the Bioterrorism Act mandating KI distribution also required the National Academy of Sciences (NAS) to produce a comprehensive scientific study of KI's efficacy, safety and distribution. This study, completed in 2004, recommended that:

- "KI should be available to everyone at risk of significant health consequences from accumulation of radioiodine in the thyroid in the event of a radiological incident"; and

- "KI distribution should be included in the planning for comprehensive radiological incident response programs for nuclear power plants. KI distribution programs should consider predistribution, local stockpiling outside the emergency planning zones (EPZ), and national stockpile and distribution capacity."

The Congress' choice of a 20-mile KI distribution radius was driven by its recognition that radiological exposure during a nuclear emergency is almost certain to exceed the "intervention level", set by the Nuclear Regulatory Commission (NRC) to 5 rem, at distances greater than 10 miles from the event. Two NRC-commissioned technical studies predicted exposure at 25 miles from the event to be over 1000 rem, with the probability of thyroid damage to an adult outdoors to be 40 percent. For infants and children, the potential for damage is much higher.[8]

Despite the unequivocal Congressional mandate, a favorable report from the NAS,[9] and the NRC's own studies, the Bush Administration delayed and obfuscated for years.

Following the 2004 NAS report, draft guidelines from HHS were published in August 2005 – two years overdue. My letter to President Bush in February 2006 expressed concern that the final HHS regulations were being held up due to spurious arguments raised by the NRC and the nuclear utility industry. In response, I received a letter in August 2006 from then-HHS Secretary Leavitt who wrote, "We are not aware of any 'alternative and more effective prophylaxis or preventive measures' that could be offered in place of potassium iodide in conjunction with other protective measures, and the President has not invoked subsection (f) of the Act. HHS has therefore proceeded with finalizing the KI distribution guidelines."

Despite those assurances from HHS, as well as a letter from me, then-House Energy and Commerce Committee Chairman John Dingell, Health Subcommittee Chairman Frank Pallone and Oversight and Investigations Subcommittee Chairman Bart Stupak that went unanswered,[10] President Bush chose to subvert the intent of the Congress, the views of his own HHS Secretary, and the recommendations of the NAS. His administration used a

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[8] NUREG/CR-1433, Sandia National Laboratories, October 1980, and NUREG/CR-6310, S. Cohen & Associates, April 1992.

[9] Similar positions are held by the World Health Organization, the American Academy of Pediatrics, the American Thyroid Association, the National Council on Radiation Protection, and the FDA, as well as the governments of Germany, Sweden and the United Kingdom.

[10] Sent 11/9/07 to OMB Director Nussle from Chairman Dingell and subcommittee chairs Markey, Stupak, and Pallone. http://energycommerce.house.gov/Press_110/110-ltr.110907.OMB.Iodide.pdf

novel interpretation of Section 127(f) of the Act, previously rejected by your agency, to prevent KI distribution. Section 127(f) was included in my amendment to allow halting of KI distribution only if superior radiation protection was achieved in the future with a newly-developed drug or method. However, instead of citing a new prophylaxis, the Bush Administration declared that evacuation and removal of contaminated foodstuffs were "more effective... preventative measures [than KI] for adverse thyroid conditions that may result from the release of radioiodide from nuclear power plants." This was a legal argument that had previously been advanced by the NRC and some in the nuclear industry to HHS, and rejected by the agency as it developed its draft KI guidelines.

Potassium iodide is a safe, convenient and highly effective way to safeguard public health against a radiological event. Not only is the science sound, but the financial mechanism to stockpile KI is already in place with the Project BioShield Act of 2004, which funds countermeasures against biological, chemical, radiological and nuclear agents ($5.6 billion through FY2013).[11] A six-day course of KI, with a 10-year shelf life, costs $1.80. *That brings the cost of protection to just 18¢ per year per person.*

In summary, in 2002 the Congress required the President to make KI available to those living nearest to our 104 currently operating nuclear power plants. The exercise of Presidential power to distribute KI is now long overdue, leaving many Americans living near these plants needlessly at risk, as sadly evidenced by the disaster in Japan. Again, I urge you to request that Office of Science and Technology Policy Director John Holdren reverse the decision made by the Bush Administration, thereby freeing up your agency to fully implement the Bioterrorism Preparedness and Response Act by making KI available to those within 20 miles of a plant.

Thank you for your consideration of this request.

Sincerely,

Edward J. Markey

Edward J. Markey

[11] The FY2004 DHS Appropriations Act (PL 108-90) and the FY2004 Emergency Supplemental Appropriations Act (PL 108-106)